P20757.A01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Yoshinobu HANYU et al.

Serial No : Not Yet Assigned

Filed : Concurrently Herewith

For : POWDER CONTAINING PHYSIOLOGICALLY ACTIVE PEPTIDE

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Prior to calculation of the filing fees and the examination of the above-identified patent application on the merits, the Examiner is respectfully requested to amend the claims as follows:

IN THE CLAIMS

Please amend the claims as follows (a marked-up copy of the claim amendments is provided as an attachment to this Amendment):

5. (Amended-Clean Text) The method claim 1 wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcholol.

7. (Amended-Clean Text) The method of one of claim 1 wherein the nonionic surfactant is selected from the group consisting of polysorbate, polyoxeyethylenehydrogenated castor oil, and a poloxamer.

8. (Amended-Clean Text) The method of claim 1 wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

9. (Amended-Clean Text) The method of claim 1 wherein the average size of the particles making up the powder is 1-10 μm.

10. (Amended-Clean Text) The method of claim 1 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide, dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

11. (Amended-Clean Text) The method of claim 1 wherein the physiologically active peptide is human growth hormone or human insulin.

12. (Amended-Clean Text) The method claim 1 wherein the physiologically active peptide is human growth hormone.

17. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcholol.

19. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the nonionic surfactant is selected from the group consisting of polyysorbate, polyoxeyethylenehydrogenated castor oil, and a poloxamer.

20. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

21. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the average size of the particles making up the powder is 1-10 μm.

22. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide,

dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

23. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the physiologically active peptide is human growth hormone or human insulin.

24. (Amended-Clean Text) The method for preparation of a powder containing a physiologically active peptide of claim 13 wherein the physiologically active peptide is human growth hormone.

27. (Amended-Clean Text) The powder containing a physiologically active peptide of claim 25 wherein the average size of the particles is 1-10 μm.

28. (Amended-Clean Text) The powder containing a physiologically active peptide of claim 25, for which drying of the aqueous liquid was performed by spray drying, spray-freeze drying, or lyophilization.

29. (Amended-Clean Text) The powder containing a physiologically active peptide of claim 25 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide, dismutase, urokinase,

proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

30. (Amended-Clean Text) The powder containing a physiologically active peptide of claim 25 wherein the physiologically active peptide is human growth hormone or human insulin.

31. (Amended-Clean Text) The powder containing a physiologically active peptide of claim 25 wherein the physiologically active peptide is human growth hormone.

32. (Amended-Clean Text) An inhalant composition containing a physiologically active peptide, wherein the inhalant composition comprises particles as defined in claim 25.

REMARKS

By the above amendment, the claims have been amended to delete multiple dependency.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,
Yoshinobu HANYU et al.

Leslie J. Paperner Reg No 33,329
Bruce H. Bernstein
Reg. No. 29,027

March 19, 2001
GREENBLUM & BERNSTEIN, P.L.C.
1941 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

MARKED-UP COPY OF AMENDED CLAIMS

5. (Amended) The method [of one of claims 1 to 4] claim 1 wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcholol.

7. (Amended) The method of one of [claims 1 to 6] claim 1 wherein the nonionic surfactant is selected from the group consisting of polysorbate, polyoxeyethylenehydrogenated castor oil, and a poloxamer.

8. (Amended) The method of [one of claims 1 to 7] claim 1 wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

9. (Amended) The method of [one of claims 1 to 8] claim 1 wherein the average size of the particles making up the powder is 1-10 μm.

10. (Amended) The method of [one of claims 1 to 9] claim 1 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide, dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

11. (Amended) The method of [one of claims 1 to 9] claim 1 wherein the physiologically active peptide is human growth hormone or human insulin.

12. (Amended) The method [of one of claims 1 to 9] claim 1 wherein the physiologically active peptide is human growth hormone.

17. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 16] claim 13 wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcholol.

19. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 18] claim 13 wherein the nonionic surfactant is selected from the group consisting of polyysorbate, polyoxeyethylenehydrogenated castor oil, and a poloxamer.

20. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 19] claim 13 wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

21. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 20] claim 13 wherein the average size of the particles making up the powder is 1-10 μm.

22. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 21] claim 13 wherein the physiologically active peptide

is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide, dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

23. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 21] claim 13 wherein the physiologically active peptide is human growth hormone or human insulin.

24. (Amended) The method for preparation of a powder containing a physiologically active peptide of [one of claims 13 to 21] claim 13 wherein the physiologically active peptide is human growth hormone.

27. (Amended) The powder containing a physiologically active peptide of claim 25 [or 26] wherein the average size of the particles is 1-10 μm.

28. (Amended) The powder containing a physiologically active peptide of [one of claims 25 to 27] claim 25, for which drying of the aqueous liquid was performed by spray drying, spray-freeze drying, or lyophilization.

29. (Amended) The powder containing a physiologically active peptide of [one of claims 25 to 28] claim 25 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon,

somatostatin, somatostatin derivatives, interferons, interleukins, superoxide, dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors and anti-vasculogenesis factors.

30. (Amended) The powder containing a physiologically active peptide of [one of claims 25 to 28] claim 25 wherein the physiologically active peptide is human growth hormone or human insulin.

31. (Amended) The powder containing a physiologically active peptide of [one of claims 25 to 28] claim 25 wherein the physiologically active peptide is human growth hormone.

32. (Amended) An inhalant composition containing a physiologically active peptide, wherein the inhalant composition comprises particles as defined in [one of claims 25 to 31] claim 25.